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7 **UNITED STATES DISTRICT COURT**
8 **WESTERN DISTRICT OF WASHINGTON**
9 **AT SEATTLE**

10 SONJA CORICH,

11 Plaintiff,

12 vs.

13 C.R. BARD, INC.,

14 Defendant.

CASE NO.

COMPLAINT FOR DAMAGES

JURY DEMANDED

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17 Plaintiff, SONJA CORICH (“Plaintiff”), files this Complaint and for causes of action
18 against Defendant C.R. Bard, Inc. (“Bard” or the “Defendant”), and alleges as follows:

19 **INTRODUCTION**

20 1. On or about January 28, 2013, at Washington Urology Surgery Center in Bellevue,
21 Washington, Plaintiff SONJA CORICH was surgically implanted by Martin Wall, M.D. with the
22 Bard Align transobturator mid-urethral sling (the “Align” or the “pelvic mesh product”), a pelvic
23 mesh product and medical device designed, manufactured, and marketed by Defendant.

24 2. Although the Align was intended to treat stress urinary incontinence, neither
25 Plaintiff nor her healthcare providers were warned that the Align was defective and negligently
26 designed and marketed. As a result of being surgically implanted with Defendant’s unreasonably

1 dangerous defective Align pelvic mesh product, Plaintiff has suffered, and continues to suffer,
2 debilitating injuries, as described further herein. In addition and in the alternative, Plaintiff suffered
3 from pre-existing injuries/conditions which were aggravated, exacerbated, and/or accelerated by
4 implantation of the Align device. Plaintiff brings this suit for damages related to those injuries.

5 **JURISDICTION AND VENUE**

6 3. The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a)
7 inasmuch as the amount in controversy exceeds \$75,000 and the Plaintiff is a citizen of a different
8 state than the Defendant.

9 4. Venue in this district for pretrial proceedings in these civil actions is proper under
10 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim
11 occurred in this district. Specifically, Petitioner was implanted with the product at issue in this
12 district by Martin Wall, M.D. in Bellevue, Washington, and was injured in this district.

13 5. Defendant is subject to *in personam* jurisdiction in the U.S. Western District Court
14 of Washington because Defendant placed defective products in the stream of commerce and all or
15 some of those products were implanted into and caused personal injuries to Petitioner, a
16 Washington resident at the time of the facts giving rise to this case, in the State of Washington.
17 Defendant has sufficient minimum contacts in Washington or otherwise intentionally avails itself
18 of the Washington market through, without limitation, its advertisement, promotion, marketing,
19 sales and/or distribution and other business activities, so as to render the exercise of jurisdiction
20 over it by the Washington courts consistent with traditional notions of fair play and substantial
21 justice.

22 **PARTIES**

23 6. Plaintiff SONJA CORICH was at all times relevant to this suit a citizen and resident
24 of the state of Washington. She currently resides in Indiana.

25 7. Defendant C.R. Bard, Inc. is a New Jersey corporation with its principal place of
26 business in New Jersey. At all times material hereto, Bard was engaged in the business of

1 developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting
2 and/or selling in interstate commerce throughout the United States, either directly or indirectly, its
3 medical devices intended to treat stress urinary incontinence and/or pelvic organ prolapse,
4 including the Align product that was implanted into Plaintiff.

5 8. Defendant is vicariously liable for the acts and omissions of its employees and/or
6 agents who were at all times relevant hereto acting on behalf of the Defendant and within the scope
7 of its employment or agency with the Defendant.

8 9. At all times relevant herein, the Defendant was engaged in the business of placing
9 medical devices into the stream of commerce by designing, manufacturing, testing, training,
10 marketing, promoting, packaging, labeling, and/or selling such devices, including the Align Pelvic
11 Mesh Product. Defendant manufactures, markets, advertises, promotes, and sells products
12 worldwide.

13 **FACTUAL BACKGROUND**

14 ***The Pelvic Mesh Products***

15 10. At all times relevant herein, Defendant was engaged in the business of developing,
16 designing, licensing, manufacturing, distributing, marketing, packaging, labeling, advertising
17 delivering, selling and introducing into interstate commerce, including within the United States
18 and within the State of Washington, either directly or indirectly through third parties or related
19 entities, a line of pelvic mesh products (the “Pelvic Mesh Products”), including the Align mesh
20 product, the device implanted into Plaintiff. The Align product was designed primarily for the
21 purpose of treating stress urinary incontinence. All references herein to Pelvic Mesh Products
22 includes the Align pelvic mesh product.

23 11. Stress urinary incontinence (“SUI”) is a type of incontinence characterized by
24 leakage of urine during moments of physical stress, such as coughing, laughing, or sneezing.
25 Although inconvenient, SUI is not life-threatening. At all relevant times, the Align was intended
26 to be used, and for Plaintiff was used, to treat stress urinary incontinence.

1 12. Surgical mesh is a medical device that is generally used to repair weakened or
2 damaged tissue. This is the type of mesh used in Defendant's Pelvic Mesh Products, including the
3 Align pelvic mesh product at issue in this case. In urogynecologic procedures, surgical mesh is
4 permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse
5 (POP) or to support the urethra to treat SUI. Most pelvic mesh products, including the Align, are
6 comprised of non-absorbable, synthetic, monofilament polypropylene mesh. Defendant's Pelvic
7 Mesh Products, including the Align pelvic mesh products, were and are specifically promoted to
8 physicians and patients as an innovative, minimally invasive procedure with minimal local tissue
9 reactions, minimal tissue trauma, and minimal pain while correcting SUI and POP.

10 13. Mid-urethral slings used for the surgical management of SUI in women are
11 primarily three different designs: the transobturator sling, the retropubic sling, and the single-
12 incision or "mini sling." The Align sling is a transobturator sling.

13 14. Prior the implantation of the Align pelvic mesh product at issue in this claim,
14 Defendant sought and obtained Food and Drug Administration ("FDA") approval to market the
15 Align under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics
16 Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially
17 equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal
18 review for safety or efficacy is required.

19 15. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of
20 SUI. These products include products manufactured, marketed, and distributed by Defendant.
21 These products were and are approved by the FDA under the abbreviated 510(k) approval process.
22 No formal review for safety or efficacy is required, and no formal review for safety or efficacy
23 was ever conducted with regard to these pelvic mesh products, including the Align pelvic mesh
24 product at issue in this case.

25 16. Despite claims that polypropylene mesh is inert, the scientific evidence shows that
26 this material as implanted in Plaintiff and others is biologically incompatible with human tissue,

1 and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair,
2 polypropylene and other surgical polymers promote a severe foreign body reaction and chronic
3 inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh
4 Products.

5 17. This "host defense response" by a woman's pelvic tissues promotes degradation of
6 the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue,
7 shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic
8 infectious response, and chronic pain. It also can cause new-onset painful sexual relations,
9 significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute
10 to the formation of severe adverse reactions to the mesh. Certain information was available in the
11 medical literature regarding the dangers of polypropylene mesh and manufacturers should have
12 been aware of this literature.

13 1. Shrinkage and bacteria lead to an evolving process and increased erosion
14 (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009;
15 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449).

16 2. Polypropylene mesh has long been known to shrink (Klinge U. Eur J Surg
17 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound
18 Obstetrics Gynecol 2007; 29:449). By 1998, polypropylene mesh was
19 known to shrink 30-50%. This was subsequently confirmed in 2007 (Klinge
20 U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn
21 R. Ultrasound Obstetrics Gynecol 2007; 29:449). Predominate
22 infection/inflammation was noted in 2007 in explanted polypropylene
23 samples (Yahi Y. Int Urogyn J 2007; 18(Suppl 1):S149).

24 3. The weave of the mesh produces very small interstices which allow bacteria
25 to enter and to hide from the host defenses designed to eliminate them. The
26 bacteria can secrete an encasing slime (biofilm) which further serves to

1 protect them from destruction by white blood cells and macrophages
2 (Osterberg B. ActaChirScand 1979; 145:431, Merritt K. J BiomatAppl
3 1991; 5:185, An Y. J Biomed Mater Res (ApplBiomat) 1998; 43:338).

4 4. The large surface area promotes wicking of fluids and bacteria which
5 provides a safe haven for bacteria which attach themselves to the mesh
6 during the insertion process (Mahmoud W. J Biomat Sci Polymer Ed 1996;
7 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int
8 Urogyn J 2009; 20:1345).

9 5. The size of the mesh placed equates to a large surface area with many places
10 for bacteria to hide while being protected from host defenses (Mahmoud W.
11 J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002;
12 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).

13 6. Polypropylene is impure: There is no such thing as pure polypropylene.
14 Polypropylene contains about 15 additional compounds which are leached
15 from the polypropylene and are toxic to tissue which enhances the
16 inflammatory reaction and the intensity of fibrosis (Sternschuss G. J Urol
17 2012; May 12 epub, Frostling H. Scand J Work Environ Health 1984;
18 10:163).

19 7. Prolene (polypropylene) was shown to be not inert in 1986 and again in
20 2003 with flaking and fissuring demonstrated by scanning electron
21 microscopy which leads to degradation and release of toxic compounds.
22 This enhances the inflammatory and fibrotic reactions (Coda A. Hernia
23 2003; 7:29, Jongebloed WL. Doc Ophthalmol 1986; 64:143–52).

24 8. With the loss of polypropylene due to degradation, the surface area is
25 greatly increased thus providing greater areas for bacterial adherence and
26 more elution of toxic compounds from the polypropylene and also the freed

toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of fibrosis (Jongebloed W. Doc Ophth 1986; 64:143, Sternschuss G. J Urol 2012; May 12 epub, Clave A. Int Urogyn J 2010; 21:261).

9. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia [painful sexual intercourse]. Cosson, M., et al., Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., Tensile properties of commonly used prolapse meshes. Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(7): p. 847-53. Margulies, R.U., et al., Complications requiring reoperation following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol, 2008. 199(6): p. 678 e1-4.
10. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor restoration of the normal properties of the vagina. Dora, C.D., et al., Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. J Urol, 2004. 171(5): p. 1970-3.
11. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery.

Curr Opin Obstet Gynecol. 2002; 14:527–595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. J Urol. 2005;65:1099–1103.

18. When the Pelvic Mesh Products, including the Align pelvic mesh product at issue in this case, are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities. Synthetic materials like polypropylene, including that used by Defendant, are known to induce an acute inflammatory response, followed by chronic inflammatory response and foreign-body reaction. A chronic inflammatory response and heightened foreign body reaction have the potential to result in failure of the device to perform safely and effectively, with significant adverse consequences for the patient. Further, a prolonged inflammatory response exposes the polypropylene mesh to a continuous bath of oxidants that may cause in vivo degradation of the mesh.

19. The polypropylene mesh used by Defendant for its Pelvic Mesh Products also contracts as a result of the development of scar tissue exacerbated by the foreign body reaction. Polypropylene mesh is known to shrink by up to over 50% during healing. When the transvaginal mesh shrinks during the normal healing process, the arms of the mesh pull on its anchoring points in the pelvic sidewall muscles, tending to pull these anchoring points and the attached muscle toward the midline. In women with these transvaginal mesh implants, including Plaintiff herein, this pulling on the pelvic sidewall muscles causes pain at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing, jumping and straining. This aggravated pulling will cause new or worsening pain to the women in whom the product is implanted. In addition, it is well established that nerves can become entrapped as a result of the chronic inflammatory response and fibrosis surrounding the mesh.

1 20. Defendant marketed the Pelvic Mesh Products, including the Align pelvic mesh
2 product, to the medical community and to patients as safe, effective, and reliable medical devices
3 that can be implanted by safe, effective, and minimally invasive surgical techniques.

4 21. Defendant marketed and sold the Pelvic Mesh Products, including the Align pelvic
5 mesh product, through carefully planned, multifaceted marketing campaigns and strategies. These
6 campaigns and strategies included, but are not limited to, aggressive marketing and the provision
7 of valuable cash and non-cash benefits to healthcare providers. Defendant also utilized documents,
8 patient brochures, and websites, offering exaggerated and misleading expectations as to the safety
9 and utility of this product.

10 22. Contrary to the representations and marketing of Defendant, the Pelvic Mesh
11 Products, including the Align pelvic mesh product, have high failure, injury, and complication
12 rates, fail to perform as intended, require frequent and often debilitating revision surgeries, and
13 have caused severe and irreversible injuries, conditions, and damage to a significant number of
14 women, including Plaintiff. The defects stem from many issues, including:

- 15 a. the use of polypropylene material in the Pelvic Mesh Products and the immune
16 reaction that results;
- 17 b. the design of the Pelvic Mesh Products to be inserted transvaginally into an area of
18 the body with high levels of pathogens that adhere to the mesh, which can cause
immune reactions and subsequent tissue breakdown;
- 19 c. the contraction or shrinkage of the mesh;
- 20 d. biomechanical issues with the design of the mesh that creates strong amounts of
21 friction between the mesh and the underlying tissue that subsequently causes that
22 tissue to degrade;
- 23 e. the use and design of trocars in the Pelvic Mesh Products that when placed correctly
are likely to pass through and injure major nerve routes in the pelvic region;
- 24 f. degradation of the mesh itself over time which causes the internal tissue to degrade;
- 25 g. the welding of the mesh itself during production, which creates a toxic substance
26 that contributes to the degradation of the mesh and host tissue; and

1 h. the design of the transobturator sling calls for placement of the polypropylene tape
2 into the obturator internus muscle of the groin, leading to direct and indirect nerve
compression, irritation, and injury of the obturator and pudendal nerves.

3 23. Upon information and belief, Defendant has consistently underreported and
4 withheld information about the propensity of its Pelvic Mesh Products, including the Align pelvic
5 mesh product, to fail and cause injury and complications, and have misrepresented the efficacy
6 and safety of these products, through various means and media, actively and intentionally
7 misleading the public.

8 24. Despite the chronic underreporting of adverse events associated with the Pelvic
9 Mesh Products, enough complaints were recorded for the Food and Drug Administration (“FDA”)
10 to issue a public health notification regarding the dangers of these devices. On October 20, 2008,
11 the FDA issued a Public Health Notification that described over a thousand (1,000) complaints
12 (otherwise known as “adverse events”) that had been reported over a three-year period relating to
13 the Pelvic Mesh Products and other similar products. Although the FDA notice did not identify
14 the transvaginal mesh manufacturers by name, a review of the FDA’s MAUDE database indicates
15 that Defendant is one of the manufacturers of the products that are the subject of the notification.

16 25. On July 13, 2011, the FDA issued a Safety Communication entitled, “UPDATE on
17 Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic
18 Organ Prolapse.” Therein, the FDA advised that it had conducted an updated analysis of adverse
19 events reported to the FDA and complications reported in the scientific literature and concluded
20 that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of “**continuing**
21 **serious concern**” (emphasis added). The FDA concluded that serious complications associated
22 with surgical mesh for transvaginal repair of pelvic organ prolapse were “not rare.” These serious
23 complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage,
24 and emotional problems. Many of the serious complications required medical and surgical
25 treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of
26 pelvic organ prolapse and stress urinary incontinence with mesh-kits was more effective than

1 traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the
2 published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ
3 prolapse repair with mesh “does not improve symptomatic results or quality of life over traditional
4 non mesh repair.” In the July 13, 2011, Safety Communication, the FDA concluded that “a mesh
5 procedure may put the patient at risk for requiring additional surgery or for the development of
6 new complications. Removal of the mesh due to mesh complications may involve multiple
7 surgeries and significantly impair the patient’s quality of life. Complete removal of mesh may not
8 be possible.” The information contained in the FDA’s Public Health Notification of October 2008
9 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendant and
10 was not disclosed in any manner.

11 26. In September 2011, the FDA acknowledged the need for additional data and noted
12 in “Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary
13 Incontinence” that the literature and information developing on SUI repair with mesh “indicates
14 that serious complications can occur...[and] a case can be made for additional premarket and/or
15 post market studies to better address the risk/benefit of all mesh products used for SUI.”

16 27. After the 2011 FDA notification that mesh complications from POP repairs were
17 "not rare," a 2013 article was published that stated: "as outlined in the FDA notifications, patients
18 should be forewarned that some transvaginal mesh complications are life altering and might not
19 always be surgically correctable. Furthermore, that study noted that "the women who received
20 both MUS and TM represented a complicated surgical group. Fifteen women (43%) required MUS
21 takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated
22 chronic pelvic pain and vaginal pain, in addition to its urinary symptoms."

23 28. In a December 2011 Joint Committee Opinion, the American College of
24 Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also
25 identified physical and mechanical changes to the mesh inside the body as a serious complication
26 associated with vaginal mesh, stating: There are increasing reports of vaginal pain associated with

1 changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections
2 of mesh...Some of these women will require surgical intervention to correct the condition, and
3 some of the pain appears to be intractable.

4 29. Plaintiff's injuries, as will be more fully established in Discovery, are of the type
5 reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

6 30. The FDA Safety Communication further indicated that the benefits of using
7 transvaginal mesh products instead of other feasible alternatives did not outweigh the associated
8 risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP
9 repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it
10 may expose patients to greater risk."

11 31. Contemporaneously with the Safety Communication, the FDA released a
12 publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of
13 Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the
14 FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo
15 POP repair with mesh are subject to mesh-related complications that are not experienced by
16 patients who undergo traditional surgery without mesh."

17 32. The FDA White Paper further stated that, "these products are associated with
18 serious adverse events...compounding the concerns regarding adverse events are performance
19 data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

20 33. In its White Paper, the FDA advises doctors to, inter alia, "[r]ecognize that in most
21 cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related
22 complications." The FDA concludes its White Paper by stating that it "has identified serious safety
23 and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ
24 prolapse."

25 34. The FDA summarized its findings from its review of the adverse event reports and
26 applicable literature stating that it "has NOT seen conclusive evidence that using transvaginal

1 placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that
2 does not use mesh, and it may expose patients to greater risk.

3 35. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended
4 for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing
5 its products immediately. In fact, the FDA has determined that the manufacturers, Bard and
6 Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for
7 these devices, which is the premarket standard that now applies to them since the agency
8 reclassified them into class III (high risk) in 2016.¹

9 36. Bard knew known about the Pelvic Mesh Products' risks and complications
10 identified in the FDA Safety Communication, ACOG/AUGS Joint Committee Opinion, and the
11 FDA Advisory that addressed the sales of transvaginal mesh implants for pelvic organ prolapse.

12 37. Defendant has further known the following:

- 13 a. that some of the predicate devices for the Pelvic Mesh Products had high
14 failure and complication rates, resulting in the recall of some of these
15 predicate devices;
- 16 b. that there were and are significant differences between the Pelvic Mesh
17 Products and some or all of the predicate devices, rendering them unsuitable
18 for designation as predicate devices;
- 19 c. that these significant differences render the disclosures to the FDA
20 incomplete and misleading; and
- 21 d. that the Pelvic Mesh Product was and is causing numerous patients' severe
22 injuries and complications.

23 38. Defendant suppressed this information and failed to accurately and completely
24 disseminate or share this and other critical information with others, including Plaintiff. As a result,
25 Defendant actively and intentionally misled and continues to mislead the public into believing that
26 the Pelvic Mesh Products and the procedures for implantation were and are safe and effective.

¹ www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants (last visited 11/30/2023).

1 39. Defendant failed to perform or rely on proper and adequate testing and research in
2 order to determine and evaluate the risks and benefits of the Pelvic Mesh Products. Defendant did
3 not, and has not, adequately studied the extent of the risks associated with its Pelvic Mesh
4 Products.

5 40. The Pelvic Mesh Products were at all times utilized and implanted in a manner
6 foreseeable to Defendant, as it generated the directions for use, created the procedures for
7 implanting the device, and trained the implanting physicians.

8 41. Defendant provided incomplete, insufficient, and misleading training and
9 information to physicians to increase the number of physicians utilizing the Pelvic Mesh Products,
10 and thus increase the sales of these products.

11 42. The injuries, conditions, and complications suffered by women who have been
12 implanted with the Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh
13 contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain
14 during sexual intercourse), blood loss, acute and chronic nerve damage and pain, obturator nerve
15 damage/neuralgia, pudendal nerve damage/neuralgia, pelvic floor damage, myofascial pain,
16 chronic pelvic/extrapelvic pain, urinary and fecal incontinence, and prolapse of organs. In many
17 cases, these women have been forced to undergo intensive medical treatment, including, but not
18 limited to, the use of pain control and other medications, injections into various areas of the pelvis,
19 spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and
20 remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

21 43. The medical and scientific literature studying the effects of polypropylene pelvic
22 mesh (like the material used in the Pelvic Mesh Products) have examined each of these injuries,
23 conditions, and complications and determined that they are in fact casually related to the mesh
24 itself and do not often implicate errors related to the implantation of the devices.

25 44. Defendant knew and had reason to know that the Pelvic Mesh Products could and
26 would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that

1 they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise
2 downplayed warnings.

3 45. At all relevant times herein, Defendant continued to promote the Pelvic Mesh
4 Products as safe and effective even when no clinical trials had been done supporting long or short-
5 term efficacy.

6 ***Defective Design***

7 46. The design of the Align transobturator sling calls for placement into the obturator
8 internus muscles in the groin, leading to an increased risk of myofascial pain and nerve
9 injury/irritation. Defendant failed to study or account for this issue when designing the device.

10 47. The Pelvic Mesh Products were designed to be permanently implanted into a
11 woman's body yet the product changes after implantation; it contracts over time which can pull or
12 compress nerves important for sexual function, mobility, bowel function, bladder function, and
13 chronic pelvic and nerve pain (neuralgia). This contraction over time, which can pull, and also
14 cause fibrosis of muscles, muscle spasms, adhesions between tissues, and inflammation which
15 impair sexual function, impaired mobility, impaired bowel and bladder function, and chronic
16 pelvic pain, neuralgia, among other mesh-related issues.

17 48. Moreover, despite claims that polypropylene mesh is inert, the scientific evidence
18 shows that this material as implanted in Plaintiff is biologically incompatible with human tissue
19 and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair,
20 polypropylene and other surgical polymers promote a severe foreign body reaction and chronic
21 inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh
22 Products, including the Align pelvic mesh product at issue herein. This "host defense response"
23 by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue,
24 causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh
25 leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain,
26 cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and

1 anatomic deformation, and can contribute to the formation of severe adverse reactions to the
2 polypropylene mesh.

3 49. The FDA defines both “degradation” and “fragmentation” as “device problems” to
4 which the FDA assigns a specific “device problem code.” “Material Fragmentation” is defined as
5 an “[i]ssue associated with small pieces of the device breaking off unexpectedly” and “degraded”
6 as an “[i]ssue associated with a deleterious change in the chemical structure, physical properties,
7 or appearance in the materials that are used in device construction.”

8 50. Defendant’s Pelvic Mesh Products, including the Align pelvic mesh product at
9 issue, were and are unreasonably susceptible to degradation and fragmentation inside the body,
10 shrinkage or contraction inside the body, intense foreign body reaction, chronic inflammatory
11 response, chronic wound healing, chronic infections in and around the mesh fibers, and nerve
12 entrapment in the collagen scar formation. Defendant knew or should have known of these serious
13 risks and should have, therefore, warned physicians and patients regarding these risks to the extent
14 they were known or knowable.

15 51. Defendant knew or should have known that its Pelvic Mesh Products, including the
16 Align pelvic mesh product at issue in this case, unreasonably exposed patients to the risk of serious
17 harm while conferring no benefit over available feasible alternatives that do not involve the same
18 risks. At the time Defendant began marketing the Align, Defendant was aware that the Align was
19 associated with each and every one of the adverse events communicated by the FDA in its July
20 13, 2011, safety communication.

21 52. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages
22 of its Pelvic Mesh Products, including the Align pelvic mesh product at issue, and advertised,
23 promoted, marketed, sold and distributed the its Pelvic Mesh Products, including the Align pelvic
24 mesh product at issue, as safe medical devices when Defendant knew or should have known that
25 the Pelvic Mesh Products were not safe for its intended purposes, and that the products would
26 cause, and did cause, serious medical problems, and in many patients, including Plaintiff,

1 catastrophic injuries. Further, while some of the problems associated with the Pelvic Mesh
2 Products, including the Align pelvic mesh product, were made known to physicians, the magnitude
3 and frequency of these problems were not disclosed and were hidden from physicians.

4 53. Contrary to Defendant's representations and marketing to the medical community
5 and to the patients themselves, its Pelvic Mesh Products, including the Align pelvic mesh product
6 at issue, have high rates of failure, injury, and complications, fail to perform as intended, require
7 frequent and often debilitating re-operations, and have caused severe and irreversible injuries,
8 conditions, and damage to a significant number of women, including the Plaintiff, making them
9 defective under the law.

10 54. Further, Defendant failed to design and establish a safe, effective procedure for
11 removal of its Pelvic Mesh Products, including the Align pelvic mesh products at issue, or to
12 determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists. Thus, in
13 the event of a failure, injury, or complications, it is impossible to easily and safely remove the
14 Pelvic Mesh Products.

15 55. Feasible, reasonable, and suitable alternative designs as well as reasonable suitable
16 alternative procedures and instruments for repair of stress urinary incontinence have existed at all
17 times relevant to this matter, including, but not limited to the following: the Burch Procedure
18 colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using
19 a product like Repliform or other biological matrix; a sling with larger pore, lighter weight mesh
20 and less polypropylene such as Ultrapro; a sling with larger pore, lighter weight mesh such as the
21 mesh used in the Ethicon Prolift+M transvaginal mesh device; a sling made of Polyvinylidene
22 fluoride (PVDF); a retropubic sling; a retropubic mini-sling, such as the TFS Surgical retropubic
23 mini sling; a retropubic mini-sling made of PVDF, such as the DynaMesh® SIS device; or a
24 retropubic mini-sling comprised of Ultrapro or other larger pore, lighter weight mesh.

25 56. The specific nature of defects for Defendant's Align pelvic mesh product at issue
26 in this case include, but are not limited to, the following:

- 1 A. The use of polypropylene in the Pelvic Mesh Products and the adverse tissue reactions
2 and host defense response that result from such material, causing adverse reactions and
3 serious, permanent injuries including, but not limited to, painful recurrent erosions and
4 associated intractable pain;
- 5 B. The design of the Align to be inserted into and through an area of the body that is blood
6 vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular
7 damage, permanent nerve injury and associated chronic, intractable neuropathic pain,
8 contaminated permanently-implanted mesh causing chronic infections, subclinical
9 infections and biofilms, enhanced chronic inflammatory response, chronic wound
10 healing with tissue destruction, as well as numerous other adverse reactions and serious
11 and permanent injuries;
- 12 C. The use and design of the trocars in the Align sling, which, when placed in the women,
13 are likely to pass through contaminated spaces and that can injure major nerve routes
14 in the pelvic region;
- 15 D. The design of the Align transobturator sling calls for placement of the tape into the
16 obturator internus muscles in the groin, leading to an increased risk of myofascial pain
17 and nerve injury/irritation;
- 18 E. Biomechanical issues with the design of the Align which results in a non-anatomic
19 condition leading to contraction or shrinkage of the mesh inside the body, that in turn
20 causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting
21 in serious and permanent injury;
- 22 F. The propensity of the mesh design characteristics of the Align mesh for plastic
23 deformation when subjected to tension both during implantation and once implanted
24 inside the body which causes the mesh, or portions thereof, to be encapsulated in a
25 rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue
26 destruction, enhanced inflammatory and fibrotic response and chronic pain;
- 27 G. The propensity of the mesh used in the Align mesh to become rigid and inflexible,
28 causing it to be improperly mated to the delicate and sensitive areas of the vagina and
29 pelvis where the product is implanted, and causing discomfort and pain with normal
30 daily activities that involve movement in the pelvic region (e.g., intercourse,
31 defecation, walking);
- 32 H. The propensity of the mesh used in the Align for degradation or fragmentation over
33 time, which causes an increased surface area that leads to enhanced chronic
34 inflammatory and fibrotic reaction, causes a “barbed wire” or “saw blade” effect by
35 the fragmented surface “sawing” through the tissue, leads to bacteria harboring in the
36 fragmented, peeled and split fiber surface which in turn leads to chronic infections at
37 the mesh surface, and results in continuing injury over time; and

- 1 I. The inability of surgeons to effectively treat many of these conditions due to the
2 integration of the mesh into the pelvic tissue and thus the inability to safely remove or
excise the mesh once a complication occurs.

3 ***Failure to Warn/Inadequate Warnings & Instructions***

4 57. At all relevant times herein, Defendant failed to provide sufficient warnings and
5 instructions that would have put the Plaintiff, her treating physicians, and the public on notice of
6 the dangers and adverse effects caused by implantation of the Pelvic Mesh Products.

7 58. The Align is also defective due to Defendant's failure to adequately warn or instruct
8 Plaintiff and/or her health care providers after the product left the manufacturer and before and
9 after implantation of the Align pelvic mesh product of subjects including, but not limited to, the
10 following:

- 11 A. The Pelvic Mesh Products' propensities, including the Align product, to contract,
retract, and/or shrink inside the body;
- 12 B. The Pelvic Mesh Products' propensities, including the Align product, for degradation,
13 fragmentation and/or migration;
- 14 C. The Pelvic Mesh Products', including the Align product, inelasticity preventing proper
15 mating with the pelvic floor and vaginal region;
- 16 D. The frequency and manner of transvaginal mesh erosion or extrusion resulting from
the Pelvic Mesh Products, including the Align product;
- 17 E. The risk of chronic inflammation resulting from the Pelvic Mesh Products, including
18 the Align product;
- 19 F. The risk of chronic infections resulting from the Pelvic Mesh Products, including the
20 Align product;
- 21 G. The risk of permanent vaginal or pelvic scarring resulting from the Pelvic Mesh
Products, including the Align product;
- 22 H. The risk of de novo urinary dysfunction resulting from the Pelvic Mesh Products,
23 including the Align product;
- 24 I. The risk of de novo dyspareunia or painful sexual intercourse resulting from the Pelvic
25 Mesh Products, including the Align product;
- 26 J. The risk of recurrent, intractable pelvic/extrapelvic pain and other pain resulting from

- the Pelvic Mesh Products, including the Align product;
- K. The risk of obturator nerve irritation/obturator neuralgia resulting from the Pelvic Mesh Products, including the Align product;
- L. The risk of pudendal nerve irritation/pudendal neuralgia resulting from the Pelvic Mesh Products, including the Align product;
- M. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products, including the Align product, which in some cases is not feasible nor possible;
- N. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products, including the Align product;
- O. Treatment of stress urinary incontinence with Defendant's Align Pelvic Mesh Product is no more effective than feasible, available and safer alternatives;
- P. Treatment of stress urinary incontinence with Defendant's Align Pelvic Mesh Product exposes patients to greater risk than feasible, available and safer alternatives;
- Q. Treatment of stress urinary incontinence with the Align Pelvic Mesh Product makes future surgical repair more difficult than feasible, available and safer alternatives;
- R. Use of the Pelvic Mesh Products, including the Align product, puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;
- S. Removal of the Pelvic Mesh Products, including the Align product, due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;
- T. Complete removal of the Pelvic Mesh Products, including the Align product, may not be possible and may not result in complete resolution of the complications, including pain; and
- U. The nature, magnitude, and frequency of the complications that could arise as a result of implantation of the Pelvic Mesh Products, including the Align product; and
- V. The Pelvic Mesh Products' defects and hazards described herein.

59. Defendant underreported and continues to underreport information about the propensity of its Pelvic Mesh Products, including the Align pelvic mesh product at issue, to fail and cause injury and complications and have made unfounded representations regarding the

1 efficacy and safety of the Pelvic Mesh Products through various means and media.

2 60. Defendant underreported and continues to underreport information about the
3 propensity of its Pelvic Mesh Products, including the Align pelvic mesh product at issue, to fail
4 and to cause injury and complications and have made unfounded representations regarding the
5 efficacy and safety of its Pelvic Mesh Products, including the Align pelvic mesh product at issue,
6 through various means and media.

7 61. Defendant failed to perform proper and adequate testing and research in order to
8 determine and evaluate the nature, magnitude and frequency of the risks attendant to its Pelvic
9 Mesh Products, including the Align pelvic mesh product at issue.

10 62. The Align pelvic mesh product at issue was at all times utilized and implanted in a
11 manner intended and/or foreseeable to Defendant, as Defendant generated the instructions for use,
12 created the procedures for implanting the devices, and trained the implanting physician.

13 63. Defendant knowingly provided incomplete and insufficient training and
14 information to physicians regarding the use of its Pelvic Mesh Products, including the Align pelvic
15 mesh product at issue, and the aftercare of patients implanted with those Pelvic Mesh Products.

16 64. At all relevant times herein, Defendant continued to promote its products as safe
17 and effective even when no clinical trials had been done supporting long-term or short-term
18 efficacy or safety. In doing so, Defendant failed to disclose the known risks and failed to warn of
19 known or scientifically knowable dangers and risks associated with its Pelvic Mesh Products,
20 including the magnitude and frequency of these risks.

21 65. At all relevant times herein, Defendant failed to provide sufficient warnings and
22 instructions that would have put Plaintiff, the medical community, Plaintiff's treating physicians,
23 and the general public on notice of the dangers and adverse effects caused by implantation of the
24 Defendant's Pelvic Mesh Products, including the Align pelvic mesh product at issue.

25 66. Defendant's Pelvic Mesh Products, including the Align pelvic mesh product at
26 issue, as designed, manufactured, distributed, sold and/or supplied by Defendant, were defective

1 as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the
2 presence of Defendant's knowledge of lack of safety.

3 67. The risk of serious injuries was known or should have been known to Defendant,
4 but in spite of these risks, Defendant continued to market the Align pelvic mesh product for
5 transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers,
6 without adequate warnings.

7 ***Resulting Injury from Defendant's Pelvic Mesh Products***

8 68. The injuries, conditions, and complications suffered by numerous women around
9 the world who have been implanted with Defendant's Pelvic Mesh Products include, but are not
10 limited to: erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ
11 perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute
12 and chronic nerve damage and pain, obturator nerve damage/neuralgia, pudendal nerve
13 damage/neuralgia, pelvic floor damage, chronic pelvic/extrapelvic pain pain, emotional distress
14 and mental anguish, and other debilitating complications. In addition, affected women, including
15 Plaintiff, will need to be continuously monitored because of being implanted with Defendant's
16 Pelvic Mesh Products.

17 69. In many of these cases, including that of the Plaintiff, women have had or will have
18 to undergo extensive medical treatment, including, but not limited to, operations to locate and
19 remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of
20 pain control and other medications, injections into various areas of the pelvis, spine, and the
21 vagina, and operations to remove portions of the female genitalia. Removal of contracted, eroded
22 and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh
23 and results in scarring on fragile compromised pelvic tissue and muscles.

24 70. The medical and scientific literature studying the effects of pelvic mesh products,
25 like that of the Align pelvic mesh product implanted in Plaintiff, has examined each of these
26 injuries, conditions, and complications, and has reported that they are causally related to the pelvic

1 mesh products.

2 ***Plaintiff's Align Implantation***

3 71. Upon information and belief, Martin Wall, M.D. recommended the Align pelvic
4 mesh product to Plaintiff as appropriate and safe for the treatment of her stress urinary
5 incontinence. Consequently, Plaintiff consented to the implantation of the Align pelvic mesh
6 product, which she underwent on or about January 28, 2013, at Washington Urology Surgery
7 Center in Bellevue, Washington.

8 72. The Align pelvic mesh product implanted in Plaintiff was in the same or
9 substantially similar condition as it was when it left Defendant's possession, and in the condition
10 directed by and expected by Defendant.

11 73. Plaintiff and her physician foreseeably used and implanted the Align pelvic mesh
12 product properly and appropriately and did not misuse or alter these products in an unforeseeable
13 manner.

14 74. Neither Plaintiff nor her healthcare providers were warned that the Align pelvic
15 mesh product was unreasonably dangerous or of the risks of the Pelvic Mesh Products, outlined
16 herein, even when used exactly as intended by Defendant. To the contrary, Defendant promoted
17 and sold the type of transvaginal mesh devices implanted in Plaintiff and thousands of women like
18 Plaintiff, to healthcare providers as a safe alternative to other procedures that did not incorporate
19 the Defendant's products.

20 75. On December 3, 2020, Plaintiff underwent a transvaginal sling revision procedure
21 with Dr. Jessica Hamner at Indiana University Health Medical Center, in order to attempt relief
22 for Plaintiff's vaginal pain and urinary issues caused by Defendant's Align sling.

23 76. As a direct and proximate cause of having the Align pelvic mesh device implanted
24 in her, Plaintiff has experienced significant physical injuries and mental and physical pain and
25 suffering, pelvic pain, extrapelvic pain, lower abdominal pain, dyspareunia, neuromuscular pain,
26 urinary and fecal problems, has undergone a revision/repair procedure and will likely undergo

1 further medical treatment and procedures, has suffered financial or economic loss, including, but
2 not limited to, obligations for medical services and expenses, and/or lost income, and other
3 damages.

4 77. As a direct and proximate result of being surgically implanted with Defendant's
5 unreasonably dangerous Align pelvic mesh product, Plaintiff has suffered, and continues to suffer,
6 debilitating injuries, including but not limited to the injuries listed above and, likely, nerve pain
7 that may be permanent. In addition and in the alternative, Plaintiff suffered from pre-existing
8 injuries/conditions which were aggravated, exacerbated, and/or accelerated by implantation of the
9 Align device. Plaintiff brings this suit for damages related to those injuries.

10 **DISCOVERY RULE AND TOLLING**

11 78. Plaintiff realleges and incorporates by reference paragraphs 1 through 77 of this
12 Complaint as if each were set forth fully and completely herein.

13 79. To the extent further pleading be necessary, Plaintiff asserts all applicable
14 contractual, state statutory, and/or common law rights and theories related to the tolling or
15 extension of any applicable statute of limitations, including equitable tolling, class action tolling,
16 delayed discovery, discovery rule, and fraudulent concealment.

17 80. Plaintiff could not have reasonably discovered her injuries and/or the occasion,
18 manner and/or means by which Defendant's breach of duty occurred until within three years of
19 the filing of this complaint. Further, Plaintiff did not and, exercising reasonable diligence,
20 including consultation with medical professionals, could not discover the existence of her legal
21 cause of action or the injuries caused by Defendant's breach of duty and/or defective products
22 until within three years of the filing of this complaint.

23 81. Moreover, Defendant continues to deny that its products are defective or cause
24 injuries such as those suffered by Plaintiff and Defendant continued to manufacture and sell the
25 products at issue and/or related or predicate products. Any applicable statute of limitations has
26 been tolled due to equitable tolling by the knowing and active concealment, affirmative

1 misrepresentations, and denial of material facts known by Defendant when Defendant had a duty
2 to disclose and/or by the application of the discovery rule. As a result of Defendant's fraudulent
3 concealment, Plaintiff and her healthcare providers were unaware, and could not have known or
4 have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged
5 herein and that those risks were the direct and proximate result of the wrongful acts and omissions
6 of Defendant.

7 **COUNT I**

8 **Negligence**

9 82. Plaintiff adopts by reference paragraphs 1 through 81, each inclusive, as though
10 fully set forth herein.

11 83. Bard directly or indirectly negligently manufactured, designed, tested, researched
12 and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold its Pelvic
13 Mesh Products across the United States and in the state of Washington, including the Align
14 implanted into Plaintiff.

15 84. At all times material hereto, Bard had a duty to Plaintiff to exercise reasonable care
16 in the design, manufacture, research and development, testing, processing, advertising, marketing,
17 labeling, packaging, distribution, promotion and sale of its Pelvic Mesh Products. Defendant had
18 a duty to exercise reasonable and ordinary care in the design, development, manufacture, testing,
19 labeling, packaging, distribution, marketing, and/or sale of the Align so as to avoid exposing others
20 to foreseeable and unreasonable risks of harm.

21 85. Defendant breached its duty of care to Plaintiff and her physicians in the design,
22 development, manufacture, testing, labeling, packaging, distribution, marketing, and sale of the
23 Align.

24 86. Defendant breached its duty in that it failed to warn Plaintiff and her physicians by
25 not reporting the risk of serious defects and life-altering complications described herein that
26

1 Defendant knew or should have known were associated with the Align prior to the time of
2 Plaintiff's implantation.

3 87. Defendant also breached its duty by receiving and failing to warn of complaints or
4 adverse events regarding the Align to the public and the medical community.

5 88. Plaintiff was a foreseeable user of the Align.

6 89. Defendant knew women like Plaintiff would be implanted with the Align.

7 90. Defendant knew or should have known that the Align's defective condition made
8 the device unreasonably dangerous or likely to be unreasonably dangerous when used in its
9 intended or reasonably foreseeable manner.

10 91. At the time of the manufacture and sale of the Align, Defendant knew or should
11 have known that the Align was designed and manufactured in such a manner so as to present an
12 unreasonable risk of harm.

13 92. The Align was unreasonably dangerous when used by Plaintiff's physician, who
14 followed the instructions provided by Defendant and used Align according to its instructions.

15 93. At the time Align left Defendant's possession, the device was in a condition that
16 made it unreasonably dangerous to Plaintiff.

17 94. At the time Plaintiff was implanted with the Align, the device was in a condition
18 that made it unreasonably dangerous.

19 95. The Align used by Plaintiff was expected to and did reach Plaintiff and her treating
20 physician without substantial change in the condition in which the device was designed, developed,
21 manufactured, tested, labeled, packaged, distributed, marketed, and/or sold by Defendant.

22 96. At all relevant times, Plaintiff's physician used the Align in the manner in which
23 was the device was intended.

24 97. As designers, developers, manufacturers, inspectors, advertisers, packagers,
25 distributors, and suppliers of Align, Defendant had superior knowledge of the product and owed a
26 duty of care to Plaintiff.

1 98. Bard breached its duty and was negligent in its actions, misrepresentations, and
2 omissions toward Plaintiff in the following ways:

- 3 a) Failing to test its Pelvic Mesh Products in a reasonable manner in order to ascertain
4 whether or not it was safe and proper for the purpose for which it was designed,
5 manufactured, labeled, promoted and sold;
- 6 b) Failing to utilize and implement a reasonably safe design in the manufacture of its
7 Pelvic Mesh Products;
- 8 c) Failing to manufacture its Pelvic Mesh Products in a reasonably safe condition;
- 9 d) Failing to warn Plaintiff or Plaintiff's health care providers of the risk of chronic,
10 disabling pain, nerve injury/irritation, and other adverse risk and complications from
11 the use of its Pelvic Mesh Products when used as instructed;
- 12 e) Failing to remove its Pelvic Mesh Products from the market when Bard knew the risks
13 outweighed the benefits;
- 14 f) Failing to accurately and completely warn Plaintiff and Plaintiff's health care providers
15 of the accurate risks and benefits of its Pelvic Mesh Products; and
- 16 g) Manufacturing its Pelvic Mesh Products, which are unreasonably dangerous and
17 defective when used as instructed.

18 99. Bard knew or should have known that its Pelvic Mesh Products had unreasonably
19 dangerous risks and caused serious injuries and complications of which Plaintiff and Plaintiff's
20 health care providers would not be aware.

21 100. It was foreseeable that Defendant's misrepresentations, actions, and omissions
22 would cause severe, permanent, and debilitating injuries to Plaintiff.

23 101. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

24 102. As a direct and proximate result of the negligent actions and inactions of Bard as
25 set forth above, Plaintiff sustained injuries including, but not limited to pelvic pain, extrapelvic
26 pain, vaginal pain, lower abdominal pain, dyspareunia, urinary and fecal issues, pain and suffering,
mental anguish, loss of capacity for the enjoyment of life, physical disfigurement, physical
impairment, and loss of earning capacity.

103. WHEREFORE, Plaintiff demands judgment of Bard for damages as described herein in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT II

Negligence—Design Defect

104. Plaintiff realleges and incorporates by reference paragraphs 1 through 103 of this Complaint as if each were set forth fully and completely herein.

105. At all times relevant, Defendant was in the business of designing, developing, manufacturing, testing, labeling, packaging, distributing, marketing, and/or selling Align, including the Align that was implanted into Plaintiff.

106. Defendant had a duty to exercise reasonable and ordinary care in the design, development, manufacture, testing, labeling, packaging, distribution, marketing, and/or sale of Align so as to avoid exposing others to foreseeable and unreasonable risks of harm.

107. Defendant breached its duty of care to Plaintiff and her physicians in the design, development, testing, labeling, packaging, distribution, marketing, and sale of the Align.

108. Plaintiff's implanting physician was a foreseeable user of Align.

109. Defendant knew women like Plaintiff would be implanted with the Align.

110. Defendant knew or should have known that Align's defective condition made the drug unreasonably dangerous.

111. The Align was unreasonably dangerous when used by Plaintiff, who followed the instructions provided by Defendant and used Align according to its common usage.

112. At the time Align left Defendant's possession, the device was in a condition that made it unreasonably dangerous to Plaintiff.

113. At the time Plaintiff was implanted with the Align, the device was in a condition that made it unreasonably dangerous.

1 114. The Align used by Plaintiff was expected to and did reach Plaintiff without
2 substantial change in the condition in which the drug was designed, developed, manufactured,
3 tested, labeled, packaged, distributed, marketed, and/or sold by Defendant.

4 115. At all relevant times, Plaintiff used Align in the manner in which was the drug was
5 intended.

6 116. As designers, developers, manufacturers, inspectors, advertisers, packagers,
7 distributors, and suppliers of the Align, Defendant had superior knowledge of the product and
8 owed a duty of care to Plaintiff.

9 117. Defendant failed to exercise reasonable and due care under the circumstances and
10 therefore breached its duty of care to Plaintiff in the following ways:

- 11 a. Failing to design the Align in a manner that protected Plaintiff from injury;
- 12 b. Designing and distributing a product in which it knew or should have known that
13 the likelihood and severity of potential harm from the product exceeded the burden
14 of taking measures to reduce or avoid harm;
- 15 c. Designing and distributing a product in which it knew or should have known that
16 the likelihood and severity of potential harm from the product exceeded the
likelihood of potential harm from other drugs available for the same purpose;
- 17 d. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's healthcare
18 providers, or the general healthcare community about Align's substantially
19 dangerous condition or about facts making the product likely to be dangerous,
including pre- and post-sale;
- 20 e. Failing to perform reasonable pre- and post-market testing of Align to determine
21 whether the product was safe for its intended use;
- 22 f. Failing to provide adequate instructions, guidelines, and safety precautions to those
23 persons to whom it was reasonably foreseeable would recommend, use, insert, and
remove Align;
- 24 g. Advertising, marketing, and recommending the use of Align, while concealing and
25 failing to disclose or warn of the dangers known by Defendant to be connected with
and inherent in the use of Align;
- 26

- 1 h. Representing that Align was safe for its intended use when, in fact, Defendant knew
2 and should have known the product was not safe for its intended purpose;
3 i. Continuing manufacture and sale of Align with the knowledge that Align was
4 dangerous and not reasonably safe;
5 j. Failing to use reasonable and prudent care in the design, research, and development
6 of Align so as to avoid the risk of serious harm associated with the use of the device;
7 k. Failing to establish and maintain an adequate post-marketing surveillance program
8 for Align;
9 l. Failing to adequately and correctly report safety information relative to Align
10 product resulting in inadequate warnings;
11 m. Failing to provide adequate and continuous warnings about the inherent danger of
12 breakage of the Align product;
13 n. Failing to warn Plaintiff and her physicians by not reporting the risk of serious
14 defects and life-altering complications described above;

15 118. It was foreseeable that Defendant's misrepresentations, actions, and omissions
16 would cause severe, permanent, and debilitating injuries to Plaintiff.

17 119. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

18 120. As a direct and proximate result of Defendant's negligence, Plaintiff has been
19 injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment
20 of life, loss of care, loss of comfort, and economic damages, including but not limited to past and
21 future medical expenses, lost income, and other damages. Plaintiff may also require additional
22 medical and/or hospital care, attention, and services in the future.

23 **WHEREFORE**, Plaintiff respectfully request this Court enter judgment in Plaintiff's
24 favor for compensatory and punitive damages, together with interest, costs herein incurred,
25 attorneys' fees and all such other and further relief as this Court deems just and proper.

26 **COUNT III**

Negligence— Failure to Warn

121. Plaintiff adopts and incorporates by reference paragraphs 1 through 120 above.

1 122. Bard researched, developed, designed, tested, manufactured, inspected, labeled,
2 distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its
3 Align Pelvic Mesh Product, and in the course of same, directly promoted or marketed the products
4 to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks
5 associated with the use of its Align Pelvic Mesh Product.

6 123. Plaintiff's use of the Align Pelvic Mesh Product was entirely foreseeable to Bard.
7 Bard expected and intended patients like Plaintiff to use its products all the while knowing its
8 products were defective and would cause serious harm.

9 124. The Pelvic Mesh Product was defective and unreasonably dangerous when it left
10 the possession of Bard in that the product contained warnings and directions which were
11 misleading and were inadequate and insufficient to alert the physicians and consumers, such as
12 Plaintiff, to the dangerous risks and complications associated with the Pelvic Mesh Product,
13 including, but not limited to chronic, disabling pain, nerve injury/irritation, and other adverse risk
14 and complications like those suffered by Plaintiff.

15 125. Defendant knew or reasonably should have known that Align was dangerous or
16 likely to be dangerous when used in its intended or reasonably foreseeable manner.

17 126. Defendant knew that the Align could cause harm and failed to warn Plaintiff of this
18 potential injury.

19 127. Defendant had a duty to warn Plaintiff, Plaintiff's physician, and/or the medical
20 community of the potential for harm.

21 128. Defendant had a continuing duty to warn Plaintiff, Plaintiff's physician, and/or the
22 medical community of the potential for harm.

23 129. At the relevant times, Defendant knew or should have known that Align was
24 designed and manufactured in such a manner as to present an unreasonable risk of harm.

25 130. Bard, one of the world's largest manufacturers, promoters, and sellers of pelvic
26 mesh products, is held to the level of knowledge of an expert in the field, and further, Bard had

1 knowledge of the dangerous risks and complications of its Pelvic Mesh Products of which it failed
2 to warn Plaintiff, and/or protect Plaintiff by informing Plaintiff's health care providers.

3 131. Plaintiff and Plaintiff's health care providers did not have the same knowledge as
4 Bard and no adequate warning was communicated to Plaintiff and/or Plaintiff's health care
5 providers.

6 132. The Align did not include an adequate warning that the Align can cause serious
7 injury to users.

8 133. Defendant failed to properly and/or adequately warn or instruct that Align can cause
9 serious injury to users.

10 134. Defendant also failed to properly and adequately warn and instruct Plaintiff and her
11 healthcare providers with regard to the inadequate research and testing of Align.

12 135. Defendant breached its duty to Plaintiff by failing to warn of the risks and dangers
13 of using Align as intended.

14 136. The warnings that accompanied the Align failed to provide the level of information
15 that an ordinary consumer and/or healthcare provider, would expect when using the product in a
16 manner reasonably foreseeable to Defendant.

17 137. Had Plaintiff or her implanting physician received proper or adequate warnings and
18 instructions as to the risks of using Align, Plaintiff would have avoided the risk and could have
19 obtained or used an alternative treatment for her stress urinary incontinence.

20 138. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

21 139. Bard had a continuing duty to warn consumers, including Plaintiff and Plaintiff's
22 health care providers, of its Pelvic Mesh Product, and the risks and dangers associated with it, and
23 negligently and/or wantonly breached its duty as follows:

- 24 a. Failed to include adequate warnings and instructions/directions for use for its Pelvic
25 Mesh Product that would alert consumers and consumer's health care providers to the
26 dangerous risks and serious complications of its Pelvic Mesh Product.

- 1 b. Failed to provide adequate post-marketing warnings and instructions after Bard knew
2 or should have known of the significant risks of injury and complications associated
3 with the use of the Pelvic Mesh Product.
4 c. Failed to inform Plaintiff and Plaintiff's health care providers that the Pelvic Mesh
5 Product had not been adequately and thoroughly tested for safety in certain classes of
6 patients.

7 140. Bard deliberately concealed and/or intentionally withheld knowledge of the risks
8 and/or complications of the Pelvic Mesh Product from Plaintiff, Plaintiff's health care providers,
9 and the medical community. By so acting, Bard acted with conscious and deliberate disregard of
10 the foreseeable harm caused by its Pelvic Mesh Product.

11 141. Although Bard knew, or was reckless in not knowing, of the defective nature of the
12 Pelvic Mesh Product, it continued to promote the Pelvic Mesh Product aggressively, without
13 providing adequate warnings and instructions concerning its use, so as to maximize sales and
14 profits at the expense of the public health and safety, in knowing, conscious, and deliberate
15 disregard of the foreseeable harm caused by these products.

16 142. As a direct and proximate result of Defendant's negligence, Plaintiff has been
17 injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment
18 of life, loss of care, loss of comfort, and economic damages, including but not limited to past and
19 future medical expenses, lost income, and other damages. Plaintiff may also require additional
20 medical and/or hospital care, attention, and services in the future.

21 143. WHEREFORE, Plaintiff demands judgment of Bard for damages as described
22 herein in an amount determined by the jury and such other and further relief as allowed in equity
23 or law.

24 **COUNT IV**

25 **Strict Liability—Failure to Warn**

26 144. Plaintiff adopts and incorporates by reference paragraphs 1 through 143 above.

145. Bard researched, developed, designed, tested, manufactured, inspected, labeled,
distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its

1 Pelvic Mesh Product, and in the course of same, directly promoted or marketed the products to
2 consumers or persons responsible for consumers, and therefore had a duty to warn of the risks
3 associated with the use of its Pelvic Mesh Product.

4 146. Plaintiff's use of the Pelvic Mesh Product was entirely foreseeable to Bard. Bard
5 expected and intended patients like Plaintiff to use its products all the while knowing its products
6 were defective and would cause serious harm.

7 147. The Pelvic Mesh Product was defective and unreasonably dangerous when it left
8 the possession of Bard in that the product contained warnings and directions which were
9 misleading and were inadequate and insufficient to alert the physicians and consumers, such as
10 Plaintiff, to the dangerous risks and complications associated with the Pelvic Mesh Product,
11 including, but not limited to chronic, disabling pain, nerve injury/irritation, and other adverse risk
12 and complications like those suffered by Plaintiff.

13 148. Bard, one of the world's largest manufacturers, promoters, and sellers of pelvic
14 mesh products, is held to the level of knowledge of an expert in the field, and further, Bard had
15 knowledge of the dangerous risks and complications of its Pelvic Mesh Products of which it failed
16 to warn Plaintiff, and/or protect Plaintiff by informing Plaintiff's health care providers.

17 149. Plaintiff and Plaintiff's health care providers did not have the same knowledge as
18 Bard and no adequate warning was communicated to Plaintiff and/or Plaintiff's health care
19 providers.

20 150. Bard had a continuing duty to warn consumers, including Plaintiff and Plaintiff's
21 health care providers, of its Pelvic Mesh Product, and the risks and dangers associated with it, and
22 negligently and/or wantonly breached its duty as follows:

- 23
- 24 d. Failed to include adequate warnings and instructions/directions for use for its Pelvic
25 Mesh Product that would alert consumers and consumer's health care providers to the
26 dangerous risks and serious complications of its Pelvic Mesh Product.
- e. Failed to provide adequate post-marketing warnings and instructions after Bard knew
or should have known of the significant risks of injury and complications associated

with the use of the Pelvic Mesh Product.

- f. Failed to inform Plaintiff and Plaintiff's health care providers that the Pelvic Mesh Product had not been adequately and thoroughly tested for safety in certain classes of patients.

151. Bard deliberately concealed and/or intentionally withheld knowledge of the risks and/or complications of the Pelvic Mesh Product from Plaintiff, Plaintiff's health care providers, and the medical community. By so acting, Bard acted with conscious and deliberate disregard of the foreseeable harm caused by its Pelvic Mesh Product.

152. Although Bard knew, or was reckless in not knowing, of the defective nature of the Pelvic Mesh Product, it continued to promote the Pelvic Mesh Product aggressively, without providing adequate warnings and instructions concerning its use, so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by these products.

153. As a direct and proximate result of Defendant's negligence, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

154. WHEREFORE, Plaintiff demands judgment of Bard for damages as described herein in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT V

Strict Liability—Defective Design

155. Plaintiff adopts and incorporates by reference paragraphs 1 through 154 above.

156. At all times material hereto, Bard engaged in the business of selling, distributing, manufacturing, marketing, labeling, and/or promoting its Pelvic Mesh Product, which was unreasonably dangerous, and therefore defective. The product was defective as designed.

1 157. At all times material hereto, Bard's Pelvic Mesh Product reached Plaintiff without
2 substantial change in the condition in which it left the possession of the Defendant and was used
3 in manner which had been contemplated and labeled.

4 158. Bard's Pelvic Mesh Product was defective and unreasonably dangerous when it
5 entered the stream of commerce and was received by Plaintiff because:

- 6 a. When placed in the stream of commerce the Pelvic Mesh Product contained
7 unreasonably dangerous design defects and were not reasonably safe as intended to be
8 used, subjecting users and consumers like Plaintiff to risks which exceeded the benefits
9 of the product;
10 b. When placed in the stream of commerce, the Pelvic Mesh Product was defective in
11 design and formulation, making the use of the product more dangerous than an ordinary
12 consumer would expect and more dangerous than other devices/procedures used to
13 surgically treat SUI;
14 c. The Pelvic Mesh Product was insufficiently and inadequately tested;
15 d. The Pelvic Mesh Product was unreasonably defective when used as intended especially
16 in light of the fact that safer alternatives existed;
17 e. The intended use of the Pelvic Mesh Product caused harmful side effects which
18 outweighed any potential utility; and
19 f. The Pelvic Mesh Product was marketed and promoted for use as a safe product, when
20 it was not safe for its intended use.

21 159. As a direct and proximate result of Defendant's negligence, Plaintiff has been
22 injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment
23 of life, loss of care, loss of comfort, and economic damages, including but not limited to past and
24 future medical expenses, lost income, and other damages. Plaintiff may also require additional
25 medical and/or hospital care, attention, and services in the future.

26 160. WHEREFORE, Plaintiff demands judgment from Bard for damages as described
herein in an amount determined by the jury and such other and further relief as allowed in equity
or law.

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COUNT VI

Fraud & Deceit

161. Plaintiff realleges and incorporates by reference paragraphs 1 through 160 of this Complaint as if each were set forth fully and completely herein.

162. At all times relevant, Defendant intentionally or recklessly misrepresented the safety of Align for its intended use.

163. Defendant knew or were reckless in knowing that its representations were false.

164. Defendant has falsely and fraudulently represented and continues to represent to the medical and healthcare community, Plaintiff and her physicians, and/or the public that Align was safe when, in fact, Align was unreasonably dangerous.

165. Defendant has falsely and fraudulently represented and continues to represent to the medical and healthcare community, Plaintiff and her physicians, and/or the public that the Align had been appropriately tested and was found to be safe and effective.

166. The representations made by Defendant was, in fact, false. When Defendant made its representations, it knew and/or had reason to know that those representations were false, and it willfully, wantonly, and recklessly disregarded the inaccuracies in its representations and the dangers and health risks to users of Align.

167. Defendant made these representations with the intent of defrauding and deceiving the medical community, Plaintiff, Plaintiff's physicians, and/or the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, and/or the public to recommend, prescribe, dispense, and purchase Align for use as a form of treatment for stress urinary incontinence, all of which evidenced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

168. In reliance upon these false representations, Plaintiff and/or her physicians were induced to, and did use Align, thereby causing Plaintiff's severe and permanent personal injuries and damages. Defendant knew or had reason to know that Plaintiff and her physicians and other

1 healthcare providers had no way to determine the truth behind Defendant's concealment and
2 omissions, which included material omissions of facts surrounding the use of Align as described
3 in detail herein.

4 169. Plaintiff and her physicians reasonably relied on facts provided by Defendant, who
5 foreseeably and purposefully suppressed and concealed facts that were critical to understanding
6 the real dangers inherent in the use of Align.

7 170. Having knowledge based on Defendant's research and testing, or lack thereof,
8 Defendant blatantly and intentionally distributed false information, including but not limited to
9 assurances to Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that the
10 Align was safe for use and was as safe or safer than other products and/or procedures available
11 and/or on the market. As a result of Defendant's research and testing, or lack thereof, Defendant
12 intentionally omitted, concealed, and suppressed the dissemination of certain results of testing and
13 research to healthcare professionals, Plaintiff, her physicians, and the public at large.

14 171. Defendant had a duty—when disseminating information to the public—to
15 disseminate truthful information, and a parallel duty not to deceive the public, Plaintiff, and/or her
16 physicians.

17 172. The information distributed to the public, the medical community, Plaintiff, and
18 her physicians by Defendant included, but was not limited to websites, information presented at
19 medical and professional meetings, information disseminated by sales representatives to
20 physicians and other medical care providers, professional literature, reports, press releases,
21 advertising campaigns, television commercials, print advertisements, and/or other commercial
22 media, and contained material representations that were false and misleading, as well as omissions
23 and concealments of the truth about the dangers of the use of Align.

24 173. These representations, and others made by Defendant, were false when made and/or
25 were made with the pretense of actual knowledge when such knowledge did not actually exist and
26 were made recklessly and without regard to the true facts.

1 174. Defendant recklessly and/or intentionally falsely represented the dangerous and
2 serious health and safety concerns inherent in the use of Align to Plaintiff, her physicians, and the
3 public at large for the purpose of influencing the sales of products that Defendant knew to be
4 dangerous and defective and/or not as safe as other alternatives.

5 175. At the time the representations were made, Plaintiff and her healthcare providers
6 did not know the truth about the dangers and serious health and/or safety risks inherent in the use
7 of Align.

8 176. Plaintiff did not discover the true facts about the dangers and serious health and/or
9 safety risks, nor did Plaintiff discover the false representations of Defendant, nor would Plaintiff
10 with reasonable diligence have discovered the true facts about Defendant's misrepresentations at
11 the time when Plaintiff used Align.

12 177. Had Plaintiff known the true facts about the dangers and serious health and/or safety
13 risks of Align, neither Plaintiff nor her physicians would have purchased, used, or relied on
14 Defendant's representations and omissions concerning Align.

15 178. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

16 179. As a direct and proximate result of Defendant's negligence, Plaintiff has been
17 injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment
18 of life, loss of care, loss of comfort, and economic damages, including but not limited to past and
19 future medical expenses, lost income, and other damages. Plaintiff may also require additional
20 medical and/or hospital care, attention, and services in the future.

21 **WHEREFORE**, Plaintiff respectfully request this Court enter judgment in Plaintiff's
22 favor for compensatory and punitive damages, together with interest, costs herein incurred,
23 attorneys' fees and all such other and further relief as this Court deems just and proper.

1 **COUNT VII**

2 **Fraud by Omission**

3 180. Plaintiff realleges and incorporates by reference paragraphs 1 through 179 in this
4 Complaint as if each were set forth fully and completely herein.

5 181. At all times relevant, Defendant intentionally or recklessly misrepresented the
6 safety of Align for its intended use.

7 182. Defendant knew or was reckless in knowing that its representations were false.

8 183. In representations to Plaintiff and/or to her healthcare providers, Defendant
9 fraudulently concealed and intentionally omitted the following material information:

- 10 a. That Align was not as safe as other products and procedures available to treat
11 stress urinary incontinence;
- 12 b. That the risk of adverse events with Align was higher than with other products
13 and procedures available to treat stress urinary incontinence;
- 14 c. That Align was not adequately tested;
- 15 d. That the limited clinical testing for Align revealed a higher risk of adverse
16 events, above and beyond those associated with other products and procedures
17 available for stress urinary incontinence;
- 18 e. That Defendant deliberately failed to follow up on the adverse results from
19 clinical studies and/or formal and informal reports from physicians and/or other
20 healthcare providers and either ignored, concealed, and/or misrepresented those
21 findings;
- 22 f. That Defendant was aware of dangers of the Align in addition to and above and
23 beyond those associated with other products and procedures available for stress
24 urinary incontinence;
- 25 g. That Align was defective, and that it caused dangerous and adverse side effects;
- 26 h. That when Align needed to be removed, the removal procedure could be
impossible; and
- i. That Align was designed negligently and designed defectively.

184. Defendant were under a duty to disclose the foregoing issues to Plaintiff.

1 185. Defendant had sole access to material facts concerning the defective nature of the
2 products and its propensity to cause serious and dangerous side effects and, hence, cause dangerous
3 injuries and damage to persons who used Align, such as Plaintiff.

4 186. Defendant knew that Plaintiff could not determine the truth of this information.

5 187. Defendant's concealment and omissions of material facts concerning the safety of
6 Align were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff,
7 Plaintiff's physicians, surgeons, and healthcare providers and to induce them to purchase,
8 prescribe, and/or dispense Align and/or to mislead them into reliance upon and cause them to use
9 Align.

10 188. At the time these representations were made by Defendant, and at the time Plaintiff
11 and/or her physicians used Align, Plaintiff and/or her physicians were unaware of the falsehood of
12 these representations and reasonably believed them to be true.

13 189. Defendant knew and had reason to know that Align could and would cause severe
14 and grievous personal injury to the users of the product and was inherently dangerous in a manner
15 that exceeded any purported, inaccurate, or otherwise downplayed warnings.

16 190. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

17 191. As a direct and proximate result of Defendant's negligence, Plaintiff has been
18 injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment
19 of life, loss of care, loss of comfort, and economic damages, including but not limited to past and
20 future medical expenses, lost income, and other damages. Plaintiff may also require additional
21 medical and/or hospital care, attention, and services in the future.

22 **WHEREFORE**, Plaintiff respectfully request this Court enter judgment in Plaintiff's
23 favor for compensatory and punitive damages, together with interest, costs herein incurred,
24 attorneys' fees and all such other and further relief as this Court deems just and proper.

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COUNT VIII

Negligent Misrepresentation

192. Plaintiff realleges and incorporates by reference paragraphs 1 through 191 of this Complaint as if each were set forth fully and completely herein.

193. Defendant had a duty to tell Plaintiff, her implanting physician, and the public the truth about the risks and harms associated with Align.

194. Defendant had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, her implanting physician, and the public that Align had been tested and found to be safe and effective for treatment of stress urinary incontinence.

195. At relevant times, Defendant breached that duty by providing Plaintiff, her healthcare providers, and the general medical community with false or incorrect information or omitted or failing to disclose material information concerning Align, including, but not limited to, misrepresentations regarding the safety of Align.

196. The information distributed by Defendant to the public, the medical community, Plaintiff, and her implanting physician, including advertising campaigns, labeling materials, print advertisements, and commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of Align.

197. Defendant's intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and her implanting physician; to falsely assure them of the quality of Align; and to induce the public and medical community, including Plaintiff and her implanting physician, to request, recommend, prescribe, insert, purchase, and continue to use Align.

198. The representations made by Defendant was, in fact, false. Align was not safe for human use in its intended and reasonably foreseeable manner. Use of Align is dangerous, as there is a risk that it may break and cause serious injury.

1 199. In reliance upon the false and negligent misrepresentations and omissions made by
2 Defendant, Plaintiff, and Plaintiff's implanting physician were induced to and did use Align,
3 thereby causing Plaintiff to endure severe and permanent injuries.

4 200. Defendant knew and had reason to know that Plaintiff, Plaintiff's implanting
5 physician, and the general medical community did not have the ability to determine the true facts,
6 which were intentionally and/or negligently concealed and misrepresented by Defendant.

7 201. Defendant had sole access to the material facts concerning the defective nature of
8 Align and its propensity to cause serious injuries.

9 202. At the time Defendant failed to disclose and misrepresented the foregoing facts,
10 and at the time Plaintiff was inserted with Align, Plaintiff and her implanting physician were
11 unaware of Defendant's negligent misrepresentations and omissions.

12 203. Defendant failed to exercise ordinary care in making representations concerning
13 Align while it was involved in the drug's manufacture, sale, testing ,quality assurance, quality
14 control, and distribution in interstate commerce because Defendant negligently misrepresented
15 Align's high risk of unreasonable and dangerous adverse side effects.

16 204. Defendant breached its duty to Plaintiff, her implanting physician, and the medical
17 and healthcare community by representing that Align has no serious side effects different from
18 older generations of similar products or procedures.

19 205. Plaintiff and Plaintiff's implanting physician reasonably relied upon the
20 misrepresentations and omissions made by Defendant, where it concealed and misrepresented facts
21 that were critical to understanding the true dangers inherent in the use of Align.

22 206. Plaintiff and her implanting physician would not have recommended and inserted
23 Align in Plaintiff had the true facts not been concealed by Defendant.

24 207. Plaintiff and Plaintiff's healthcare providers' reliance on the foregoing
25 misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.
26

208. Defendant knew, and had reason to know, that Align had been insufficiently tested or had not been tested at all; that the products lacked adequate and accurate warnings; that it created a high risk, and/or higher than acceptable risk, and/or higher than reported risk that it represented a risk of adverse side effects, including pain and suffering, surgery to remove the product, and other severe and personal injuries, which are permanent and lasting in nature.

209. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

210. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IX

Breach of Express Warranty

211. Plaintiff realleges and incorporates by reference paragraphs 1 through 210 of this Complaint as if each were set forth fully and completely herein.

212. Through Defendant's public statements, descriptions, and promises regarding Align, Defendant expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for stress urinary incontinence, and that the products were adequately tested and fit for its intended use.

213. At relevant times, Defendant was aware that consumers, including Plaintiff, would use Align, which is to say that Plaintiff was a foreseeable users of Align.

1 214. Plaintiff and/or her inserting physicians were, at all relevant times, in privity with
2 Defendant.

3 215. The Align was expected to reach and did in fact reach its ultimate consumer,
4 including Plaintiff and her inserting physicians, without substantial change in the condition in
5 which it was manufactured and sold by Defendant.

6 216. Defendant breached various express warranties with respect to Align, including the
7 following particulars:

- 8
- 9 a. Defendant represented to Plaintiff and her physicians and healthcare providers
10 through its labeling, advertising, marketing materials, detail persons, seminar
11 presentations, publications, notice letters, and regulatory submissions that
Align was safe, and fraudulently withheld and concealed information about the
substantial risks of serious injury associated with using Align;
 - 12 b. Defendant represented to Plaintiff and her physicians and healthcare providers
13 that Align was as safe and/or safer than other alternative procedures and
14 treatments, and fraudulently concealed information that demonstrated that
Align was not safer than alternatives available; and
 - 15 c. Defendant represented to Plaintiff and her physicians and healthcare providers
16 that Align was more efficacious than other alternatives and fraudulently
concealed information regarding the true efficacy of the product.

17 217. In reliance upon Defendant's express warranties, Plaintiff was inserted with Align
18 as prescribed and directed, and therefore, in the foreseeable manner normally intended,
19 recommended, promoted, and marketed by Defendant.

20 218. At the time of making such express warranties, Defendant knew or should have
21 known that Align does not conform to these express representations because Align was not safe
22 and had numerous side effects, many of which Defendant did not accurately warn about, thus
23 making Align unreasonably unsafe for its intended purpose.

24 219. Members of the medical community, including Plaintiff's implanting physician and
25 other healthcare professionals, relied upon the representations and warranties of Defendant in
26 connection with the use, recommendation, description, and/or dispensing of Align.

1 228. Defendant knew or had reason to know that Plaintiff would rely on Defendant's
2 judgment and skill in providing Align for its intended use.

3 229. Plaintiff and/or her physicians and surgeons were at all relevant times in privity
4 with Defendant.

5 230. Defendant's Align was expected to reach and did in fact reach consumers, including
6 Plaintiff and/or her physicians and surgeons, without substantial change in the condition in which
7 it was manufactured and sold by Defendant.

8 231. Defendant breached various implied warranties with respect to Align, including the
9 following particulars:

- 10 a. Defendant represented through its labeling, advertising, marketing materials,
11 detail persons, seminar presentations, publications, notice letters, medical
12 literature, and regulatory submissions that the Align was safe, and fraudulently
13 withheld and concealed information about the substantial risks of serious injury
14 associated with using the Align;
- 15 b. Defendant represented that the Align was safe and/or safer than other alternative
16 treatments or procedures and fraudulently concealed information that
17 demonstrated that Align was not as safe or safer than alternatives; and
- 18 c. Defendant represented that the Align was more efficacious than other
19 alternative treatments and fraudulently concealed information regarding the
20 true efficacy of the Align.

21 232. In reliance upon Defendant's implied warranties, Plaintiff and/or her inserting
22 physicians and surgeons used the Align as prescribed in the foreseeable manner normally intended,
23 recommended, promoted, and marketed by Defendant.

24 233. Defendant breached its implied warranties to Plaintiff and/or her inserting
25 physicians and surgeons in that Align was not of merchantable quality, safe, and fit for its intended
26 use, or adequately tested, in violation of common law principles.

 234. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

 235. As a direct and proximate result of Defendant's breach, Plaintiff has been injured,
suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life,

1 loss of care, loss of comfort, and economic damages, including but not limited to past and future
2 medical expenses, lost income, and other damages. Plaintiff may also require additional medical
3 and/or hospital care, attention, and services in the future.

4 **WHEREFORE**, Plaintiff respectfully request this Court enter judgment in Plaintiff's
5 favor for compensatory and punitive damages, together with interest, costs herein incurred,
6 attorneys' fees and all such other and further relief as this Court deems just and proper.

7 **COUNT XI**

8 **Violation of Consumer Protection Laws**

9 236. Plaintiff realleges and incorporates by reference paragraphs 1 through 235 of this
10 Complaint as if each were set forth fully and completely herein.

11 237. Plaintiff purchased and used Align primarily for personal use, thereby suffering
12 ascertainable losses from Defendant's actions in violation of consumer protection laws.

13 238. Had Defendant not engaged in the deceptive conduct described herein, Plaintiff and
14 her physicians would not have purchased and/or paid for Align and would not have incurred related
15 medical costs and injury.

16 239. Defendant engaged in wrongful conduct while at the same time obtaining, under
17 false pretenses, moneys from Plaintiff for Align that was inserted into Plaintiff and that would not
18 have been paid had Defendant not engaged in unfair and deceptive conduct.

19 240. Unfair methods of competition or deceptive acts or practices that were proscribed
20 by law include the following:

- 21
- 22 a. Representing that goods or services have characteristics, ingredients, uses,
benefits, or quantities that it does not have;
- 23 b. Advertising goods or services with the intent not to sell them as advertised; and
- 24 c. Engaging in fraudulent or deceptive conduct that creates a likelihood of
25 confusion and/or misunderstanding.
- 26

1 241. Plaintiff was injured by the cumulative and indivisible nature of Defendant's
2 conduct. The cumulative effect of Defendant's conduct directed at patients, physicians, and
3 consumers, including Plaintiff and her physicians, was to create demand for and promote the sale
4 of Align. Each aspect of Defendant's conduct combined to artificially create sales of Align.

5 242. Defendant has a statutory duty to refrain from unfair or deceptive acts or trade
6 practices in the design, labeling, development, manufacture, promotion, and sale of Align.

7 243. Had Defendant not engaged in the deceptive conduct described above, Plaintiff
8 would not have purchased and/or paid for Align and would not have incurred related medical costs.

9 244. Defendant's deceptive, unconscionable, or fraudulent representations and material
10 omissions to patients, physicians, and consumers, including Plaintiff and her physicians,
11 constituted unfair and deceptive acts and trade practices in violation of state and federal consumer
12 protection statutes.

13 245. Defendant's actions, as complained of herein, constitute unfair competition or
14 unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of state and
15 federal consumer protection statutes.

16 246. Defendant has engaged in unfair competition or unfair or deceptive acts or trade
17 practices or have made false representations in violation of state and federal consumer protection
18 statutes, which serve to protect consumers against unfair, deceptive, fraudulent, and
19 unconscionable trade and business practices and false advertising. Defendant is the supplier,
20 manufacturer, advertiser, and seller who is subject to liability under such legislation for unfair,
21 deceptive, fraudulent, and unconscionable consumer sales practices.

22 247. Defendant violated the statutes that were enacted to protect consumers against
23 unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising
24 by knowingly and falsely representing that Align was fit to be used for the purpose for which it
25 was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These
26 representations were made in uniform promotional materials and product labeling.

1 248. Defendant's deceptive, unconscionable, unfair and/or fraudulent
2 misrepresentations and material omissions to Plaintiff constituted consumer fraud and/or unfair
3 and deceptive acts and trade practices in violation of the Washington Consumer Protection Act.

4 249. The actions and omissions of Defendant alleged herein are uncured or incurable
5 deceptive acts under the statutes enacted in the states to protect consumers against unfair,
6 deceptive, fraudulent, and unconscionable trade and business practices and false advertising.

7 250. Defendant had actual knowledge of the defective and dangerous condition of Align
8 and failed to take any action to cure such defective and dangerous condition.

9 251. Plaintiff and her inserting physicians and surgeons relied upon Defendant's
10 misrepresentations and omissions in determining which product to use and/or procedure to
11 undergo and/or perform.

12 252. Defendant's deceptive, unconscionable, or fraudulent representations and material
13 omissions to patients, physicians, and consumers constitute unfair and deceptive acts and practices.

14 253. By reason of the unlawful acts engaged in by Defendant, and as a direct and
15 proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

16 254. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

17 255. As a direct and proximate result of Defendant's violation of the consumer
18 protection statutes, Plaintiff has been injured, suffered severe and permanent pain, suffering,
19 disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic
20 damages, including but not limited to past and future medical expenses, lost income, and other
21 damages. Plaintiff may also require additional medical and/or hospital care, attention, and services
22 in the future.

23 **WHEREFORE**, Plaintiff respectfully request this Court enter judgment in Plaintiff's
24 favor for compensatory and punitive damages, together with interest, costs herein incurred,
25 attorneys' fees and all such other and further relief as this Court deems just and proper.

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COUNT XII

Punitive (Exemplary) Damages (New Jersey Law)

256. Plaintiff realleges and incorporates by reference paragraphs 1 through 255 of this Complaint as if each were set forth fully and completely herein.

257. Pursuant to New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, Bard is, thus, liable to Plaintiff for punitive (exemplary) damages in an amount to be determined by the enlightened conscience of the jury, based on the clear and convincing evidence to be presented at trial, in an amount sufficient to deter Bard and others from future similar conduct.

PRAYER FOR RELIEF

WHEREFORE, Petitioner demands trial by jury, and pray for judgment against Defendant as follows:

1. A judgment against Defendant holding it liable for compensatory damages in a reasonable amount determined to be fair and just by the jury in this cause sufficient to adequately compensate Petitioner for her harms and losses, including but not limited to damages:

- a. For past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;
- b. For past and future economic and special damages, according to proof at the time of trial;
- c. For past and future medical and incidental expenses, according to proof at the time of trial;
- d. For past and future loss of earnings and impaired earning capacity, according to proof at the time of trial;
- e. For past and future physical impairment;
- f. For past and future physical disfigurement; and
- g. For past and future pain and suffering, as well as mental and emotional distress, according to proof at the time of trial.

2. For punitive (exemplary) damages under New Jersey law;

3. For costs, attorneys' fees, interest, or any other relief, monetary or equitable, to

which she is entitled; and

4. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Petitioner hereby demands trial by jury as to all issues in the above captioned matter.

Dated this 1st day of December, 2023.

Respectfully submitted,

DOLAN LAW FIRM, P.C.

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